## Medicare Rx Update: May 22, 2006

**CMS Administrator applauds the strong partnership between CMS and pharmacists...**
At an afternoon speech at NCPA's 38th Legislation and Government Conference, CMS Administrator, Dr. Mark McClellan reflected on where we've been…and where we are going with Part D, the DRA and the PQA. "Pharmacy perspectives are now an essential and integral part of our agency, just as prescription drugs are an absolutely essential part of modern medicine and now, for the first time, an integral part of Medicare… The implementation of the drug benefit was a once-in-a-lifetime challenge for all of us, but the heightened level of interaction between CMS and our nation's pharmacists is here to stay."

**… but Deficit Reduction Act (DRA) implementation was the topic of the day**
Dr. McClellan told a capacity crowd that, "Pharmacists have made it clear to us that unless AMPs are defined and calculated accurately... AMPs will not accurately reflect prices available to retail pharmacies. We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement. We also recognize that pharmacists are especially concerned about the DRA provision that calls for AMPs to be posted beginning on July 1, 2006, because the more specific definition of AMP would not be reflected in the current AMP data as reported by manufacturers."

"Consequently, I am announcing today that CMS will not publicly release the current AMP figures. They just aren't the right numbers to use. We do expect to share pricing information with the states, as we do confidentially with other types of drug pricing data, but only for purposes of helping them set up their billing systems appropriately and not for the purposes of setting reimbursements. Instead, we are focusing our efforts on developing a proposed regulation that will assure an accurate and effective AMP calculation ahead of implementation of the drug payment reforms."

To view Dr. McClellan's remarks in their entirety, please see the attached document.

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**Remarks of Mark B. McClellan, MD, PhD**
**As delivered to the**
**NCPA 38th Legislation and Government Conference**
**May 22, 2006**

Thank you, Bruce Roberts, for that introduction, and thank you, too, Jim Rankin. The NCPA has been a leading voice in helping us achieve our shared goal of achieving high-quality pharmacy care, in Medicare Part D, in Medicaid—where there are some very important pharmacy reforms underway—and throughout our health care system.

I want to thank you all for having me back, once again. I believe that this is the third year in a row that I've had the opportunity to meet with you. You all have worked closely with us day in and day out—and night in and night out—on some of the most important issues facing our health care system. I'm particularly grateful to Bruce and his team, especially Doug Hoey, Charlie Sewell, and Stacey Swartz; who have been wonderful partners, and to Larry Kocot, who has been the CMS point person on these very key issues.

Additionally, I especially want to thank all of the members of the National Community Pharmacists Association, for your work with us. All of you have worked long, hard hours to bring badly needed prescription drug coverage to people with Medicare.

As a direct result of your efforts, enrollment in the drug benefit has exceeded expectations, and millions of prescriptions are being filled each day. Every day, we are taking steps together to improve the drug benefit and improve the health care system. At this historic time, the importance of our close relationship has never been greater, and I can't tell you how much I appreciate it.

Over the past year I've traveled all over the country. I've visited community and institutional pharmacies, I've talked with pharmacists, and I've been getting daily updates from CMS and HHS staff on their communications with pharmacists. What I've learned is that there are few things more important than working effectively with all of you to get quality health care to our beneficiaries.

Now, as we shift our focus from enrollment and initial implementation of the Medicare drug benefit, to integrating the new prescription benefit with our broader initiatives on promoting prevention and high quality care, we will need to continue to work together just as closely.

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Before I turn to those next steps, I think it's important to review just how much has happened with the most important new Medicare benefit in more than 40 years.

One thing that's been clear over the months that have passed since I last spoke with you— and especially since January 1—is that pharmacists have been tremendous

partners. Among the tens of thousands of partnerships we forged to launch this benefit effectively, no partnership was more important than this one.

Starting with NCPA's national leadership, many national, state and local pharmacy organizations partnered with us. You gave us access to your newsletters and e-mail lists, as well as to your standards organizations and technical societies. We met together at hundreds of town hall and state pharmacy association meetings around the country and on conference calls and Open Door Forums too numerous to count. We dedicated a portion of the CMS website to our efforts with you.

This wasn't just "outreach" or an "education campaign." Rather, it's been a two-way street where we actively sought your counsel and participation to identify and address implementation issues.

We know we can't provide quality care without ongoing and high-level attention to pharmacist issues. Since I joined the agency two years ago, we've put pharmacists on our staff in our central office and every one of our regional offices for the first time ever.

I want to be clear that this was not a one-time effort to gear up for the drug benefit—it's a permanent change in the level of pharmacist involvement in the management of our programs. Pharmacy perspectives are now an essential and integral part of our agency, just as prescription drugs are an absolutely essential part of modern medicine and now, for the first time, an integral part of Medicare.

These ongoing contacts and technical interactions have paid off in giving us the ability to find and fix the start-up issues that arose in launching the Medicare drug benefit. The implementation of the drug benefit was a once-in-a-lifetime challenge for all of us, but the heightened level of interaction between CMS and our nation's pharmacists is here to stay.

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This partnership contributed to high levels of participation in the drug benefit. Many of you who have provided assistance with questions about drug coverage decisions know this already, but we had a significant surge in interest and enrollment in the final weeks before enrollment in Medicare prescription drug coverage closed for most people with Medicare on May 15 – and many of these beneficiaries got their questions answered by the person they trusted the most to answer their questions—their local community pharmacist.

While we are still tabulating final enrollment numbers, we can report that more than 38 million people with Medicare now have good, secure coverage for prescription drugs. Enrollment in Part D-related coverage accounts for over 32 million of these beneficiaries. Just 5 months after the drug benefit began enrollment is stronger than expected, in no small part as a result of your efforts.

These enrollment numbers are an important part of the story, but the other important part is the first-hand experience of pharmacists across the country.

Part of this is what pharmacists have told us about the impact of new drug coverage on our beneficiaries. Like the experience of an Arkansas pharmacist who, for the first time, didn't have to advise his Medicaid beneficiaries about which prescriptions to fill, because now there were no limits on the number of prescriptions. Or the patients who had been buying drugs outside of the safety of US pharmacies, or skipping their medicines, but now are coming back to their local pharmacists.

Behind each of these success stories all over the country, pharmacists were central to making the program work. This was especially true in early January, when over 20 million people, including people with the most complex drug needs, started their new Medicare coverage.

With your help and ideas, CMS worked around the clock to find start-up problems and fix them. While we were doing this, pharmacists were doing what it took to get beneficiaries the prescriptions they needed—even when you had to cope with gaps in billing information for certain beneficiaries, and with unacceptably long wait times on pharmacy help lines.

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Because of our partnership with you, CMS was able to move quickly to address Part D implementation issues on these and many other fronts. So I want to thank you for that, as well.

Many of the initial start-up difficulties were the result of millions of late-month enrollments and plan switches. We've addressed this in part by getting the message out about allowing a reasonable amount of time between when someone enrolls in a plan and when that person can use coverage.

We've also taken further steps with the drug plans and states to assure accurate and complete coverage data is available to pharmacists when beneficiaries first show up in the pharmacy.

For example, plans are now using twice-a-month updates on coverage and co-pay status for their enrollees in the low-income subsidy.

We are tracking the accuracy of plan data—which has now achieved very high levels.

We've established "business processes" with plans so they can quickly and automatically confirm the current eligibility and co-pay status of beneficiaries in our systems, and amend information if they are having difficulty with prescriptions.

Consequently, we have seen major declines in the rate of casework requests we are getting, particularly related to dual and LIS eligibility and enrollment.

We also responded quickly to pharmacist feedback by investing in substantial enhancements in our call centers, in particular a toll-free number at Medicare exclusively for pharmacists to obtain beneficiary enrollment information or answer other questions. We worked hard to ensure that answer times for this dedicated, toll-free pharmacist line were well under a minute. We also made large additional investments in customer service representatives to handle calls from pharmacists and beneficiaries quickly.

And, we dealt directly and forcefully with plans where customer and pharmacy service was inadequate, instructing them to increase the numbers of customer service representatives in their own call centers and take other necessary steps to provide timely and effective responses to inquiries.

The result has been substantial improvements in call center service. Since January, wait times on our 1-800-MEDICARE customer service line have consistently averaged under 2 to 4 minutes. Even with the extraordinary interest on May 15—when we shattered our previous record of around 400,000 calls by handling over 640,000 calls in one day—we achieved an average wait time of less than 13 minutes. By the way, that previous record was set on January 2.

We've also seen major improvements in the prescription drug plans, with the vast majority of plans now answering the vast majority of customer and pharmacist calls in less than 5 minutes.

This reinforces our ability to get coverage problems resolved. Quicker access for pharmacists who call a plan is coupled with the ability of the plan to do an immediate lookups of Medicare coverage information, and to the plan's having an effective business processes to resolve complaints. I want to thank you again for helping us to focus efforts effectively on resolving plan coverage problems, and I expect we will continue to work together on these issues going forward.

We also took action to smooth access to medications, especially in the start-up period. In January, I called on the plans to extend the transitional supply of off-formulary medications from 30 to 90 days. We instructed plans to continue to cover a patient for the year if the patient had been stabilized on a covered medication when they enrolled, even if the plan subsequently took their drug off formulary.

CMS instructed plans that their typical window for pharmacies to submit claims during this initial phase must be expanded, from the typical 30 to 90 days to 180 days. I viewed this as an essential step. Pharmacists were not always able to obtain appropriate or adequate billing information, yet they dispensed medications to meet their patients' needs

anyway. We want to make sure that pharmacists get paid for these costs for all beneficiaries with Medicare coverage.

The number of these cases has gone way down also as a result of our collaboration to create and improve the "E1" system. If an enrollee does not have a card or proof of enrollment in a prescription drug plan—and some do not when they show up at the pharmacy counter to use their new coverage for the first time—you can use the E1.

This system, which we developed collaboratively with pharmacy groups, is providing real-time eligibility determinations on your existing computer systems, and rapid responses to queries. It has a very high level of complete information, particularly for LIS-enrolled beneficiaries.

At the same time, we've seen a big decline in the number of queries. Many more people with Medicare have accurate billing information with them when they go to the pharmacy, as a result of steps to get that information to the beneficiary and in the computer systems sooner.

For example, on January 4, this system received nearly 1.5 million inquiries. By January 31st, it dropped to around 300,000, then to only 120,000 on May 1 and has been running right around that level ever since. Since January 1, pharmacists have been able to identify correct plan information for beneficiaries more then 14 million times using the E1 system.

We also worked with pharmacy software companies and continue to assist pharmacists in the use of our backup systems, including our "point-of-sale" prescription billing system for dual-eligible beneficiaries without Part D billing information.

Providing accurate information to pharmacies, timely processes for obtaining any information that is incomplete, and backup methods for billing when necessary, has all been a top priority for us. But we've aimed to do more to drive down the administrative costs in your pharmacy. Your input led us to work with you, and other pharmacy and health plan organizations, to support an unprecedented effort to standardize electronic responses in pharmacy computer systems.

A major payoff for this effort came in early April, when a group of pharmacy and plan organizations, including America's Health Insurance Plans, NCPA and NACDS, along with others such as the American Pharmacists Association, and the Pharmaceutical Care Management Association—a collection of groups that you don't often see at the same podium making an announcement together—released a set of response codes to simplify and standardize pharmacy procedures when a prescription is not approved by a plan.

The initial step in this unique collaboration was to provide pharmacists with a clearer understanding of why a claim was being rejected by a Medicare Plan, without having to take time out for a phone call.

There is now a set of standardized reject codes and messaging, to streamline electronic claims processing and reduce the burden on pharmacists. The collaboration has also transmitted a second set of recommendations on prior authorization requirements; daily dose limitations; quantities that may be dispensed for a given prescription, and age and gender contraindications. These will further improve service to Medicare beneficiaries and cut down on the phone calls that add up to a lot of time spent on administration instead of helping people.

This kind of collaborative process to get to system-wide standards to reduce burdens on pharmacies is fundamentally important.

We've already noted that we view these codes as best practice that should be adopted by the drug plans, and drug plans have responded. However, to make sure this happens, today I'm announcing that we are notifying the drug plans that the approved reject codes are not just best practices, but come July they will be Medicare requirements.

Other standard codes and messaging approved by the National Council for Prescription Drug Programs will also become Medicare requirements within 90 days of NCPDP action. This requirement will continue to reduce administrative burdens not only in Medicare, and also achieve more consistent codes across all health insurance plans.

It's an example of what we can do together to reduce your administrative burden and the way we want to continue to work with you as time goes on.

We also listened to pharmacists concerns about co-branding with drug store logos on cards. Accordingly, to build on the steps we have already taken to enable Medicare beneficiaries to find out about convenient community pharmacies in each drug plan—and to avoid any potential enrollee confusion about where they can purchase their medication—co-branding on pharmacy benefit cards will be prohibited for the upcoming plan year.

I also want to be clear that we take very seriously any instance in which drug plans are not living up to their contractual payment requirements. If you have a complaint related to payment failing to meet the terms of your contract, bring it to us.

We have investigated every pharmacy payment issue presented to us to make sure that plans are paying pharmacies in accordance with their contracts. And we will remain vigilant to make sure that all parties continue to live up to their financial commitments.

In addition, we recently completed another review of the payment approaches used by the leading prescription drug plans. We found that up to 18 out of the top 20 prescription drug plans pay pharmacy claims on a twice-a-month billing cycle of 15 days or less. As you know, from industry billing practices that often take longer, a 15-day billing cycle generally provides pharmacies with payment within 21 - 25 days. These top plans account for more than 90 percent of the drug coverage for Medicare beneficiaries.

Finally, to ensure that quality service by plans to their network pharmacists is a continuing part of the Medicare prescription drug program, CMS let plans know that customer service to pharmacies will be used to measure effectiveness and contract compliance to determine their future participation in Medicare. We are collecting measures of plan complaint rates now and expect to make them public, to help beneficiaries make more informed decisions about their coverage in 2007.

As a result of all of these efforts, pharmacists are telling us that while we still have important issues to address together, the system has markedly improved. But I want to be clear that we are not sitting back or reducing our vigilance in any way. Quite the opposite. The early months of the drug benefit have taught us is that we need to keep working together closely to continue to improve the drug benefit from the standpoint of pharmacists.

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We also intend to work closely with the pharmacy community to implement the pharmacy provisions in the Deficit Reduction Act (DRA). I know how important it is to independent pharmacists for us to get this right from the beginning. These days, even the conversations I have with pharmacists about the Medicare drug benefit turn pretty quickly to some of the key issues we need to address in implementing the DRA.

And so I want to commend your NCPA leadership for the constructive dialogue we have had since the DRA was enacted just three months ago. In addition to NCPA, I also want to recognize the productive discussion we have had with NACDS. I know Bob Hannan is here with Tony Civello. I'm glad you all are here, because I want to get some news out to all of community pharmacy, as well as to manufacturers and wholesalers.

As you know, the DRA will affect the way the Medicaid program calculates its Federal Upper Limit, used to determine the maximum level of reimbursement for drugs with generic competitors. This provision of the DRA represents a clear opportunity for states to save money on generic product acquisition costs. But actual savings will be dependent upon state actions with the new FUL.

For example, if states do not maintain the right incentives for generic utilization, any savings will be lost to higher and more expensive brand-name utilization. For this reason, CMS guidance encourages states to align incentives for generic utilization and

consider paying pharmacists more in dispensing fees to support state savings from greater use of generics.

We think investing in pharmacy value through steps like this makes good policy sense for states. "More financial support to pharmacists that improve quality and reduce costs of drug coverage and chronic disease management…" is actually one of the key elements of our guidance to states in our *Road Map to Medicaid Reform* released in March, and I encourage you to take a look at the details.

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Under another provision of the DRA, as many of you know, CMS is required to collect and publicly post Average Manufacturer Prices to better inform the states and the public about the true price of prescription drugs. The goal of this DRA provision is to capture the most accurate pricing data possible to assure that the Federal government and state Medicaid programs are paying appropriately for generic drugs.

Pharmacists have made it clear to us that unless AMPs are defined and calculated accurately and include only prices that are available to the "retail class of trade," AMPs will not accurately reflect prices available to retail pharmacies. We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement.

We also recognize that pharmacists are especially concerned about the DRA provision that calls for AMPs to be posted beginning on July 1, 2006, because the more specific definition of AMP would not be reflected in the current AMP data as reported by manufacturers.

Consequently, I am announcing today that CMS will not publicly release the current AMP figures. They just aren't the right numbers to use. We do expect to share pricing information with the states, as we do confidentially with other types of drug pricing data, but only for purposes of helping them set up their billing systems appropriately and not for the purposes of setting reimbursements.

Instead, we are focusing our efforts on developing a proposed regulation that will assure an accurate and effective AMP calculation ahead of implementation of the drug payment reforms.

We will be releasing this revised definition for public comment as a proposed rule. And we will also be developing an initial round of AMP data based on the new definition for public comment.

I firmly believe that public discussion of the best approach to the definition of AMP is essential for effective implementation, and I want to put out the numbers later this year that will enable us to work with you most effectively next year to support this.

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I've had a lot of ground to cover in a matter of minutes, and I appreciate your staying with me as I've reviewed all of these important reforms. But I want to conclude by taking a step back and talking about the big picture for the future of retail pharmacy.

I know there are a lot of concerns about tighter reimbursement rates per prescription. I can relate to this, having experienced the same kind of tightening in third-party payments in my own medical practice.

I know there is some interest in potentially seeing new kinds of payment regulation from the Federal government. But speaking as a physician, government regulation of payments is not something I'd recommend to any health professional.

I've experienced first-hand the blunt effort to reduce health care costs by cutting payments to providers, because no one made the effort to find a better approach to keep quality health care affordable. I've lived through the frustration of watching my workload increase while payment rates not only went down, but got locked in and didn't keep up to support new and promising directions in higher-quality care.

Tighter payments per service, like tighter payments per prescription, have been part of a broad and fundamental trend in health care systems around the world. Such tightening of payment rates has occurred universally—universally when government gets involved in setting payments. But it's not a long-term solution to the challenges in health care we are facing today, and in particular, the challenges in community pharmacy.

Instead, focusing on spending health care dollars better, rather than just on reducing payment rates to reduce health care costs, deserves strong support from Medicare and we are going to make it happen. Pharmacists and pharmacies have already demonstrated the great value they provide in the implementation of the Medicare drug benefit. They have also shown they can add much more—helping people find lower cost drugs like generics and therapeutic alternatives, helping people with multiple illnesses understand how to use their medications, and improving compliance.

All of these things can improve quality of care and reduce overall health care costs. This helps us get to a health care system that provides the right care for every person every time.

On April 19, I announced the establishment of the Pharmacy Quality Alliance. The establishment of the PQA is an important step toward a pharmacy business model that rewards real value delivered rather than just volume of prescriptions dispensed.

The PQA is a win-win approach that drives us to the most effective way to control costs—that is, recognizing and supporting pharmacists in providing high quality care and keeping overall health care costs down. It will build the track record for the coming launch of Medication Management Therapy, which promotes appropriate medication use, reduces the risk of adverse events, and optimizes therapeutic outcomes.

It will help us move forward on evidence-based MTM so that MTM will be meaningful and practical. Most importantly, it will help us align incentives and recognize and reward the value that pharmacists bring to the overall healthcare equation. We need widely accepted benchmarks for quality to make that happen.

Over the last few years, we've made progress in other aspects of health care. We've been pleased to support private-public partnerships—the Hospital Quality Initiative, the Ambulatory Care Quality Alliance, and the Nursing Home and Home Health Quality Initiatives—which have brought together major stakeholders and created consensus on valid, meaningful measures of health care quality and efficiency. Evidence-based measures that are broadly accepted by health professionals, that represent what we should be supporting in health care—but too often don't.

The PQA will provide you with the means to promote coordination of care and to make sure that patients are getting the most appropriate and most cost-effective therapy available. It will support you in doing what you do best. NCPA and NACDS have already demonstrated a strong commitment to the PQA. I hope this leadership will continue and that all pharmacy organizations, as well as manufacturers, wholesalers and PBMs will continue to participate in this process because we need the input and support of a broad community of interest to shape benchmarks and measures as we go forward.

Our objective is to collect valid information on the quality of pharmacy services. We also want to report information that is meaningful to consumers, plans, and providers so they can make informed choices. Then we can get out of the vicious circle of rising costs and lower payment rates, and truly support a pharmacy business model based on quality and not just volume. Your expertise is absolutely essential to making sure we do this right.

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Now, the May 15 enrollment deadline is behind us. It's time to take some next steps. We've are closing the coverage gap in Medicare, and now we need to close the prevention gap and the quality gap. As you know, many patients have their diseases diagnosed late, and even when they have drug coverage, they often fail to comply with the medications that have been proven to prevent complications and keep health care costs down, or they use medicines incorrectly. It's time for us to work together to change that.

To make that happen, we intend to join the efforts of the PQA with the same grassroots networks and personalized support systems for drug benefit enrollment to improve the effective use of the drug coverage, as well as the use of other preventive benefits in Medicare.

The steps we've taken to bring the drug benefit on-line—community-based outreach, unprecedented partnerships, much greater support for beneficiaries and caregivers—have helped to get Medicare beneficiaries and their caregivers more involved in their care. It's an indispensable way to prevent complications—this "one-on-one" with patients that prevents them from showing up in an emergency room. It means better coverage and higher quality care as well.

We have much more to do together to improve the quality of pharmacy care, but we've also got a unique opportunity to make it happen.

We are grateful to the pharmacy community for your commitment and hard work. Your participation was essential to achieving a Medicare prescription drug benefit—the most important addition to the program in its 40-year history.

I look forward to continuing to work closely with you to make sure we achieve the promise of 21st Century health care—which can only happen if we recognize and support the leadership of community pharmacy in delivering high-quality care.

Thank you very much.